

<b>Case Number:</b>	CM15-0118623		
<b>Date Assigned:</b>	06/26/2015	<b>Date of Injury:</b>	04/30/2008
<b>Decision Date:</b>	09/01/2015	<b>UR Denial Date:</b>	06/08/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/19/2015

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: New York

Certification(s)/Specialty: Pediatrics, Internal Medicine

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 55 year old female, who sustained an industrial injury on 4/30/2008. The mechanism of injury is unclear. The injured worker was diagnosed as having headache, neck sprain/strain, right shoulder strain/sprain and adhesive capsulitis, degenerative joint disease of the knee (noted to be improved), and chronic pain syndrome (noted to be worse). Treatment to date has included chiropractic treatment, CT scan of the head and chest, corticosteroid injection, orthovisc injection, laboratory evaluations, magnetic resonance imaging of the right shoulder, physical therapy, and urine drug screening. The request is for Gralise, Cymbalta, and Zipsor. A PR-2 dated 5/26/2015, revealed she complained of pain to the neck, bilateral knees, right shoulder, and right wrist. She rated her pain 5-8/10, and described it as achy, throbbing, shooting, tingling, dull, radiating, numbing, and cramping. She reported her pain to be better with medications and rest. Her current pain is noted to be 7/10, least reported pain over the period since her last assessment 5/10, average pain 8/10, and pain after taking the opioid 4/10, and pain relief is for 2 hours. Objective findings noted she was positive for numbness, headaches, joint pain, lightheadedness, muscle stiffness, muscle weakness, depression, anxiety, and stress. The treatment plan included: orthopedic evaluation, chiropractic care, neurology follow up, Gralise, Cymbalta, and Zipsor. The records indicate she has been utilizing Gralise and Zipsor since at least December 2014, possibly even longer. She is noted to have had adverse side effects with use of Neurontin taken 3 times daily, and therefore is to utilize Gralise once per day. The provider noted she has had a reduction in numbness and radicular pain allowing for an

increase in activities of daily living and overall function with the use of Gralise. She is noted to have failed trials with Neurontin and Lyrica.

### **IMR ISSUES, DECISIONS AND RATIONALES**

The Final Determination was based on decisions for the disputed items/services set forth below:

**Gralise 600mg 1-2 Tabs P.O. Qd #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs) Page(s): 16-22. Decision based on Non-MTUS Citation Drugs.com.

**Decision rationale:** Per Drugs.com, Gralise is also known as Gabapentin and used in the treatment of post-herpetic neuralgia. Gabapentin is an anti-epilepsy drug (AED). The CA MTUS guidelines recommend anti-epilepsy drugs for neuropathic pain. "A good response to the use of AEDs has been defined as a 50% reduction in pain and a moderate response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the trigger for: a switch to a different first line agent, combination therapy if treatment with a single drug agent fails". Ongoing treatment should reflect documentation of pain relief and functional improvement, as well as, side effects of the anti-epilepsy drug. The ODG guidelines do not recommend Gralise as a first-line agent for restless legs syndrome, and indicate there is no evidence to support its use for neuropathic pain conditions or fibromyalgia without a trial of generic Gabapentin regular release. The records do indicate a failure of Neurontin. The records indicate there is no significant reduction of pain, and that her pain had worsened slightly in intensity after taking the "opioid". The efficacy of the use of Gralise specifically, and functional improvement with its use is not noted in the records for this injured worker. Therefore, the request for Gralise 600 mg 1-2 tabs by mouth daily #60 is not medically necessary.

**Cymbalta 30mg 1 tab Qid #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain; Cymbalta Page(s): 13-16, 42.

**Decision rationale:** Per the CA MTUS guidelines, Cymbalta (Duloxetine) is an antidepressant in the class called selective serotonin and norepinephrine reuptake inhibitors (SNRIs). The CA MTUS guidelines recommend antidepressants as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. The CA MTUS states that Duloxetine is FDA approved for anxiety, depression, diabetic neuropathy, and fibromyalgia. It is used off

label for neuropathic pain and radiculopathy. The CA MTUS indicates there is not high quality evidence reported to support the use of Duloxetine for lumbar radiculopathy, and that more studies are needed to determine the efficacy of duloxetine for other types of neuropathic pain. The records do not indicate specific pain outcomes in regards to the use of Cymbalta, or give an evaluation of function, sleep quality and duration, or a psychological assessment. In addition the requested dosing of 30 mg 4 times daily is in excess of the CA MTUS recommended dosing of 60mg once daily. Therefore the request for Cymbalta 30mg, one tablet 4 times daily #120 is not medically necessary.

**Zipsor 25mg 1 tab Qd Prn #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Functional restoration approach to chronic pain management; NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 8-9, 67-73. Decision based on Non-MTUS Citation Drugs.com.

**Decision rationale:** Per Drugs.com, Zipsor is the brand name for Diclofenac potassium liquid filled capsules. The CA MTUS guidelines state that Diclofenac is a non-steroidal anti-inflammatory drug (NSAID). According to the CA MTUS all therapies must be focused on the goal of functional restoration rather than just the elimination of pain and assessment of treatment efficacy is accomplished by reporting functional improvement. The CA MTUS does not recommend Diclofenac Potassium dosing greater than 150mg per day orally, and note that different formulations of Diclofenac are not necessarily bioequivalent. The request is for Zipsor 25mg, one tablet every day as needed, #30. The CA MTUS recommends NSAIDs (non-steroidal anti-inflammatory drugs) at the lowest dose for the shortest period in patients with moderate to severe pain in those patients with osteoarthritis (including knee and hip). According to the CA MTUS all therapies must be focused on the goal of functional restoration rather than just the elimination of pain and assessment of treatment efficacy is accomplished by reporting functional improvement, with functional improvement being documented in reduction of pain, increased pain control, and improved quality of life. Her current pain was noted to be 7/10 and unchanged. Her least reported pain over the period since her last assessment is noted to have increased slightly from the assessment previously. Her average pain remained unchanged. Her pain after taking the "opioid" was noted to be 3/10 on 4/13/2015, and 4/10 on 5/26/2015. She continued to have pain relief for 2 hours. The records do not indicate if these pain assessments were specifically related to Zipsor or her other pain medications. She is reported to be taking Gralise, Zipsor, and Cymbalta. Additionally, she has been utilizing Zipsor since at least December 2014, possibly longer. The Zipsor is noted to have been utilized long term. Therefore, the request for Zipsor 25mg, one tab every day as needed #30 is not medically necessary.